



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/633,349 | 08/01/2003 | Donald A. Sargent | ST8725US | 3719 |
| 22203 | 7590 | 11/14/2006 | EXAMINER | |
| KUSNER & JAFFE HIGHLAND PLACE SUITE 310 6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143 | | | CHORBAJI, MONZER R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1744 | |

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,349

Applicant(s)

SARGENT ET AL.

Examiner

MONZER R. CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 and 25 is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-23 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This final action is in response to the amendment received on 08/31/2006

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1744

4. Claims 1-13 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky (U.S.P.N. 5,552,115) in view of Bond et al (U.S.P.N. 4,445,551).

Regarding claims 1, 7 and 12, Malchesky teaches the following: a container (figure 4:C) with a generally cup-shaped tray that includes a bottom wall and a continuous side wall, bottom and side walls defining a cavity (figure 4:62, 60, col.6, lines 64-67 and col.7, lines 1-6), a lid attachable to the tray, a fluid inlet in the tray communicating with the cavity (figure 4:72), a fluid outlet in the tray communicating with the cavity (figure 4:70) where each of the inlet and the outlet has a valve assembly (figure 4:74) such that when the tray is placed in the decontamination chamber (figure 2:10 and lid B in figure 1), the valves moves into an open position for allowing liquid sterilant to enter and exit the tray and when the tray is removed from the decontamination chamber the valves moves into a closing position for sealing the container (col.7, lines 5-6, lines 26-30) and a circulation system (col.6, lines 24-27) such that the cavity is in communication with the circulation system through the valves when the container is placed in the decontamination chamber. However, Malchesky fails to teach using a flexible valve element being integrally formed and having a movable part and a fixed part in the container that is moved by a mechanical actuator in the decontamination chamber such that the valve element is disposed away from the surface toward the cavity when in open position and the valve element engages the surface when in closed position. Bond teaches placing an integrally formed (col.3, lines 55-67, col.4, lines 33-54 and col.5, lines 27-57) movable valve (figure 4:22, 21 and

col.8, lines 17-26) on a container (col.8, lines 10-13) such that using a mechanical actuator (figure 10:70 and col.6, lines 40-44) axially moves the valve (figure 10: 36 and 73 and figures 11-12). In addition, Bond discloses that the flexible valve element includes a first portion (figure 4:22) movable relative to the container (figure 9:B) and a second portion (figure 2:21) fixed relative to the container (figure 9:B) such that the valve element is disposed away from the surface toward the cavity when in open position (figures 11 and 12:22 and 70) and the valve element engages the surface when in closed position (figure 10:22 and 70). Furthermore, the first portion (figure 4:22) is capable of being connected by a plurality of radially extending arms (figure 4:22 and 45) to the second portion (figure 6:21, 22, 45 and figure 11:21, 22, 45 and 77). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Malchesky apparatus by substituting one liquid transfer means (check valves) for another (movable actuated valves) since both of the movable valve and the mechanical actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

Regarding claims 13 and 19-20, Malchesky teaches the following: a circulation system (col.6, lines 24-27) with a first fluid inlet line (figure 2:32) and a fluid outlet line (figure 3:36) that communicates with the first fluid inlet port (figure 4:72) and the fluid outlet port (figure 4:70) of a container (figure 4 C) when the container is disposed in the decontamination chamber (col.7, lines 5-6, lines 26-30), a microbial liquid decontamination solution (col.5, lines 53-55) and an essentially closed loop circulation system for circulating the liquid sterilant (col.6, lines 24-27).

Regarding claims 2, 5-6, 8-9, 16 and 21, Malchesky discloses a tray with multiple inlets and an outlet (figure 4:72 and 70) where each inlet and outlet includes check valve (figure 4:74). Malchesky fails to teach the following: flexible valve element with first portion movable relative to the tray and the second portion is fixed to the tray, each of the flexible valve elements is formed of a resilient flexible material, valve assembly is movable by an actuator element on the decontamination chamber, valve assembly includes a flexible valve element having a normally closed position, each actuator physically contacts the first movable portion of the flexible valve element and moves it to the open position when the container is placed in the decontamination chamber and a second fluid inlet with a flexible valve element. Bond teaches the following: a flexible valve element having a first portion movable (figure 4:22) relative to the container (figure 9:B) and a second portion fixed (figure 2:21) to the container (figure 4:22, figure 3:22 and 24 and col.8, lines 17-26), each of the flexible valve elements is formed of a resilient flexible material (col.3, lines 20-23), valve assembly is independently movable by an actuator element on the container (figure 10:70, col.6, lines 40-44 and col.8, lines 10-13) between an open position and a closed position in order for the fluid to be transferred, valve assembly includes a flexible valve element having a normally closed position (col.6, lines 18-20) and each actuator physically contacts the first movable portion (figure 4:22) of the flexible valve element (figure 6:21 and 22) and moves it to the open position (col.8, lines 17-26 and figure 10:70). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Malchesky apparatus by substituting one liquid transfer means (check valves) for

another (movable actuated valves) since both of the movable valve and the mechanical actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

Regarding claims 3-4, 10 and 17-18, Malchesky discloses a tray with multiple inlets and an outlet (figure 4:72 and 70) where each inlet and outlet includes check valve (figure 4:74) such that when the tray is placed in the decontamination chamber (figure 2:10 and lid B in figure 1), the valves allow liquid sterilant to enter and exit the tray (figure 4:C) and when the tray is removed from the decontamination chamber the valves seal the container (col.7, lines 5-6, lines 26-30). This means that when the tray is not in the decontamination chamber, the valve elements are normally in a closed position and when the tray is placed in the decontamination chamber the valves are in an open position. Malchesky fails to teach the use of flexible valve elements and that each of the flexible valve elements has a first movable portion that is moved by an external flexible actuator element. Bond teaches the use of flexible valve elements (figure 4:22, figure 3:22 and 24, col.8, lines 17-26 and col.3, lines 20-23) and that each of the flexible valve elements has a first movable portion (figure 4:22) that is moved by an external flexible actuator element (figure 10:70). In addition, Bond teaches that the plastic actuator element can be a part of a standard threaded connector (col.6, lines 42-44). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Malchesky apparatus by substituting one liquid transfer means (check valves) for another (movable actuated valves) since both of the

movable valve and the mechanical actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

Regarding claims 11 and 22-23, Malchesky teaches the following: a container (figure 4:C) with an inlet and an outlet such that each has a check valve (figure 4:72, 70 and 74), a fluid inlet is in communication with a nozzle within the container (col.7, lines 38-41) and fluid inlet is in fluid communication with fluid connectors connectable with medical instruments in the container (col.7, lines 30-35).

5. Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky (U.S.P.N. 5,552,115) in view of Bond et al (U.S.P.N. 4,445,551) and further in view of Langford (U.S.P.N. 5,906,802).

Regarding claim 26, Malchesky teaches the following: a container (figure 4:C) with a generally cup-shaped tray that includes a bottom wall and a continuous side wall, bottom and side walls defining a cavity (figure 4:62, 60, col.6, lines 64-67 and col.7, lines 1-6), bottom wall having openings (figure 4:62), a lid attachable to the tray, a fluid inlet in the tray communicating with the cavity (figure 4:72), a fluid outlet in the tray communicating with the cavity (figure 4:70) where each of the inlet and the outlet has a valve assembly (figure 4:74) such that when the tray is placed in the decontamination chamber (figure 2:10 and lid B in figure 1), the valves moves into an open position for allowing liquid sterilant to enter and exit the tray and when the tray is removed from the decontamination chamber the valves moves into a closing position for sealing the container (col.7, lines 5-6, lines 26-30). Malchesky fails to teach the following: using a flexible valve element being integrally formed and having a movable part and a fixed

part in the container that is moved by a mechanical actuator in the decontamination chamber such that the valve element is disposed away from the surface toward the cavity when in open position and the valve element engages the surface when in closed position and the opening in the bottom of the tray defining a surface on the bottom wall of the tray cavity. Bond teaches placing an integrally formed (col.3, lines 55-67, col.4, lines 33-54 and col.5, lines 27-57) movable valve (figure 4:22, 21 and col.8, lines 17-26) on a container (col.8, lines 10-13) such that using a mechanical actuator (figure 10:70 and col.6, lines 40-44) axially moves the valve (figure 10: 36 and 73 and figures 11-12). In addition, Bond discloses that the flexible valve element includes a first portion (figure 4:22) movable relative to the container (figure 9:B) and a second portion (figure 2:21) fixed relative to the container (figure 9:B) such that the valve element is disposed away from the surface toward the cavity when in open position (figures 11 and 12:22 and 70) and the valve element engages the surface when in closed position (figure 10:22 and 70). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Malchesky apparatus by substituting one liquid transfer means (check valves) for another (movable actuated valves) since both of the movable valve and the mechanical actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

Bond fails to teach opening in the bottom of the tray defining a surface on the bottom wall of the tray cavity. Langford discloses valves (figure 9:94A-B) that correspond to openings in the bottom of the tray (figure 9:90 and col.7, lines 12-29) such that each opening in the bottom of tray 90 defines a surface (unlabeled tops of

valves 94A-B in figure 9 upon engagement with the tray) on the bottom wall of the tray cavity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Malchesky tray by having its inlets and its outlets in the bottom surface as taught by Langford since inlets and outlets in the bottom of a tray results in the creation of pumping action (Langford, col.7, lines 25-30) resulting in an improved medical items cleaning apparatus.

Regarding claims 27 and 30-31, Malchesky discloses a tray with multiple inlets and an outlet (figure 4:72 and 70) where each inlet and outlet includes check valve (figure 4:74) connected to the tray. Malchesky and Langford fail to teach that each of the flexible valve elements is formed of a resilient flexible material and that the valve elements each independently movable between an open and a closed position. Bond teaches the following: a flexible valve element having a first portion movable (figure 4:22) relative to the container (figure 9:B) and a second portion fixed (figure 2:21) to the container (figure 4:22, figure 3:22 and 24 and col.8, lines 17-26), each of the flexible valve elements is formed of a resilient flexible material (col.3, lines 20-23) and a valve assembly that is independently movable (figure 10:70, col.6, lines 40-44 and col.8, lines 10-13) between an open position and a closed position. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Malchesky apparatus by substituting one liquid transfer means (check valves) for another (movable actuated valves) since both of the movable valve and the mechanical actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

Regarding claims 28-29, Malchesky discloses a tray with multiple inlets and an outlet (figure 4:72 and 70) where each inlet and outlet includes check valve (figure 4:74) such that when the tray is placed in the decontamination chamber (figure 2:10 and lid B in figure 1), the valves allow liquid sterilant to enter and exit the tray (figure 4:C) and when the tray is removed from the decontamination chamber the valves seal the container (col.7, lines 5-6, lines 26-30). This means that when the tray is not in the decontamination chamber, the valve elements are normally in a closed position and when the tray is placed in the decontamination chamber the valves are in an open position. Malchesky and Langford both fail to teach that each of the flexible valve elements has a first movable portion that is moved by an external flexible actuator element. Bond teaches that each of the flexible valve elements has a first movable portion (figure 4:22) that is moved by an external flexible actuator element (figure 10:70). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Malchesky apparatus by substituting one liquid transfer means (check valves) for another (movable actuated valves) since both of the movable valve and the mechanical actuator can be molded from plastic and this constitutes an economic advantage (Bond et al., col.2, lines 21-22).

Allowable Subject Matter

6. Claims 24-25 are allowed.

Response to Arguments

7. Applicant's arguments filed on 08/31/2006 have been fully considered but they are not persuasive.

Art Unit: 1744

On page 13 of the Remarks/Arguments section, Applicant argues that neither Malchesky nor Bond teaches that the first portion is connected to the second portion by a plurality of radially extending arms. The examiner disagrees. Bond discloses that the flexible valve element includes a first portion (figure 4:22) movable relative to the container (figure 9:B) and a second portion (figure 2:21) fixed relative to the container (figure 9:B) such that the first portion (figure 4:22) is capable of being connected by a plurality of radially extending arms (figure 4:22 and 45) to the second portion (figure 6:21, 22, 45 and figure 11:21, 22, 45 and 77).

On bottom of page 13 to page 14 of the Remarks/Arguments section, Applicant argues that both Malchesky and Bond fail to teach an opening in the bottom wall of the cavity where the opening defines a surface on the bottom wall of the cavity that surrounds the opening. The newly applied reference (Langford) discloses plurality of valves (figure 9:94A-B) that correspond to openings in the bottom of the tray (figure 9:90 and col.7, lines 12-29) such that each opening in the bottom of tray 90 defines a surface (unlabeled tops of valves 94A-B in figure 9 upon engagement with the tray) on the bottom wall of the tray cavity.

On page 14 of the Remarks/Arguments section, Applicant argues that Bond sliding valve structures have surfaces that are not exposed to a liquid deactivation composition. The examiner recognizes that this feature the applicant recites is not disclosed in the instant claims. In addition, as the rejection stands with regard to independent claims 1, 7, 12 and 26, the movable actuated valve of Bond upon being

substituted for the check valve of Malchesky is capable of being exposed to the sterilant. See MPEP 2114 with respect to evaluating apparatus claims.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.
11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1744

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MRC



GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER